

ZETIN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZETINZETIN?

ZETINZETIN contains the active ingredient acitretin and belongs to a group of medicines called retinoids. It is used to treat psoriasis and keratinisation disorders. ZETINZETIN capsules should only be taken by children where alternative therapy cannot be used.

For more information, see Section [1. Why am I using ZETINZETIN?](#) in the full CMI.

2. What should I know before I use ZETIN?

Do not use if you have ever had an allergic reaction to retinoids or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ZETIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZETIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZETIN?

- ZETIN capsules should be swallowed whole with a glass of water or milk.
- Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.
- Tell your doctor if you are pregnant or breastfeeding or plan to become pregnant.

More instructions can be found in Section [4. How do I use ZETIN?](#) in the full CMI.

5. What should I know while using ZETIN?

Things you should do	<ul style="list-style-type: none">• you are about to be started on any new medicine.• you are about to have any blood tests.• you are going to have surgery or an anaesthetic or are going into hospital.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Give this medicine to anyone else, even if their symptoms seem similar to yours.• Take your medicine to treat any other condition unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ZETIN affects you.• Decreased night vision has been reported with acitretin therapy. Be careful when driving or operating any vehicle at night.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in its original packaging until it is time to take it.• If you take your medicine out of its original packaging it may not keep well.• Keep your medicine in a cool dry place where the temperature will stay below 25°C.

For more information, see Section [5. What should I know while using ZETIN?](#) in the full CMI.

6. Are there any side effects?

Common side effects can include dryness of the lips, mouth, nose, eyes and skin, drying and inflammation of mucous membranes, thirst, flushing, difficulty producing tears, intolerant of contact lenses, itchiness, redness or rashes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZETIN

Active ingredient: *Acitretin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZETIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZETIN.**

Where to find information in this leaflet:

- [1. Why am I using ZETIN?](#)
- [2. What should I know before I use ZETIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZETIN?](#)
- [5. What should I know while using ZETIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZETIN?

ZETIN contains the active ingredient acitretin. It is used to treat psoriasis and keratinization disorders.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

Acitretin, the active ingredient of ZETIN, belongs to a group of medicines called retinoids. It is very similar to Vitamin A which is obtained from our diet and is vital for the normal growth and development of the body, especially the skin.

Psoriasis is a skin disease with thickened patches of red skin, often with silvery scales. ZETIN is used to treat severe psoriasis and other severe skin disorders.

ZETIN works to return skin to normal when problems with the normal development of the skin are present, as in the case of severe psoriasis and some other skin disorders.

There is no evidence that this medicine is addictive.

Use in children.

ZETIN capsules should only be taken by children where alternative therapy cannot be used.

2. What should I know before I use ZETIN?

Warnings

Do not use ZETIN if you have or have had any of the following:

- severe kidney disease
- severe liver disease
- abnormally high levels of fat in your blood

- you are allergic to acitretin, retinoids or Vitamin A or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You are pregnant or you intend to become pregnant in the next 36 months.

Check with your doctor if you:

- You are taking tetracycline antibiotics. These include doxycycline HCl, Doxine, Doxy, Achromycin and Minomycin.
- You are taking vitamin A, or preparations that contain vitamin A.
- You are taking methotrexate.
- You are hypersensitive to, or have had an allergic reaction to, acitretin or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

The expiry date (EXP) printed on the pack has passed.

The packaging is torn, shows signs of tampering or it does not look quite right.

Donation of blood by a patient being treated with ZETIN is prohibited during and for three years after completion of treatment with ZETIN.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

High risk patients

In patients with diabetes, alcoholism, obesity, cardiovascular risk factors or a lipid metabolism disorder undergoing treatment with ZETIN, more frequent checks are necessary of serum values for lipids, and/or glycaemia and other cardiovascular risk indicators, e.g. blood pressure. For all high - risk patients where cardiovascular risk indicators fail to return to normal or deteriorate further, dose reduction or withdrawal of acitretin should be considered

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Any possibility that you may be

pregnant must be ruled out by both you and your doctor before you start taking ZETIN capsules. The result of a pregnancy test with a minimum sensitivity of 25mIU/mL and **MUST** be negative when performed within two weeks before beginning of ZETIN treatment. ZETIN is highly teratogenic, inducing a high frequency of severe and life-threatening birth defects i.e. there is an extremely high risk of having a baby that is severely deformed.

This means you must use effective contraception (preferably 2 complementary methods) for one month before, during and 3 years after treatment with ZETIN.

You must also tell your doctor immediately if you become pregnant in the 3 years following the end of treatment.

Full patient information about the teratogenic risk and the strict pregnancy prevention measures as specified in the Pregnancy Prevention Programme should be given by the physician to all patients, both male and female

You are Breastfeeding.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Breastfeeding must stop before ZETIN treatment can start. Do not breastfeed while taking ZETIN capsules.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

- You have allergies to any other medicines any other substances, such as foods, preservatives or dyes.
- You have or have had any medical conditions, especially the following:
 - diabetes, or family members with diabetes
 - liver disease
 - high triglycerides
 - cholesterol levels in the blood, or family members with a history of high blood triglycerides or cholesterol levels
- You are currently pregnant, or you plan to become pregnant. Do not take this medicine whilst pregnant.
- You are currently breastfeeding, or you plan to breastfeed. Do not take this medicine whilst breastfeeding.
- You are planning to have surgery.
- You are currently receiving or are planning to receive dental treatment.
- You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with ZETIN.

These include:

- tetracycline antibiotics (such as Vibramycin, Doxine, Doxy, Achromycin and Minomycin)
- phenytoin
- methotrexate
- alcohol containing medicines.
- the "mini-pill", a low-dose progestogen oral contraceptive
- vitamin A, or formulations that contain vitamin A

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with ZETIN.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZETIN.

4. How do I use ZETIN?

Carefully follow all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines. This may also consider your bodyweight and whether you develop any side effects.

The starting dose is usually either 25 mg (1 x 25 mg capsule) or 30 mg (3 x 10 mg capsules) per day for 2 to 4 weeks.

Your dose will probably then be adjusted by your doctor when it is known how you respond to ZETIN capsules.

The initial signs of improvement may be seen in the first week but, more often, after 2 or 3 weeks. It may take 2 to 3 months until the full effect is seen.

Do not change your dosage without first checking with your doctor.

Affected skin areas will either peel off or steadily clear. Sometimes more redness or itching may be present at first, but this will normally improve as treatment continues.

How to take it

ZETIN capsules should be swallowed whole with a glass of water or milk.

When to take ZETIN

- Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.
- Female patients should wait until the 2nd or 3rd day of their menstrual period before starting ZETIN capsules.
- This helps to ensure that you are not pregnant before you start to take ZETIN therapy.

How to take it for

- Continue taking your medicine for as long as your doctor tells you.
- A temporary increase in psoriasis is sometimes seen when first starting treatment.
- Make sure you have enough to last over weekends and holidays.

If you forget to use ZETIN

ZETIN should be used regularly at the same time each day.

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you use too much ZETIN

In the event of acute overdose, ZETIN must be withdrawn at once. Symptoms of overdose are

Headache, vertigo, nausea or vomiting, drowsiness, irritability and pruritus.

If you think that you have used too much ZETIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ZETIN?

Things you should do

Call your doctor straight away if you:

- you are about to be started on any new medicine.
- you are about to have any blood tests.
- you are going to have surgery or an anaesthetic or are going into hospital.

It is critical to keep all of your appointments with your doctor so your progress with ZETIN therapy can be monitored regularly.

Your doctor may ask you to do some blood, liver function and other tests from time to time in order to check your progress and pick up any unwanted side effects.

Inform your doctor if, for any reason, you have not taken this medicine exactly as prescribed.

Otherwise, your doctor may think this medicine was not effective and change your treatment unnecessarily.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you should not do.

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- The effects of UV light are enhanced by retinoid therapy; therefore, patients should avoid excessive exposure to sunlight and the unsupervised use of sun lamps. Where necessary a sun - protection product with a high protection factor of at least SPF 15 should be used.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZETIN affects you.

Decreased night vision has been reported with acitretin therapy. Be careful when driving or operating any vehicle at night.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it.
- If you take your medicine out of its original packaging it may not keep well.
- Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor as soon as possible if you do not feel well while you are taking ZETIN or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • dryness of the lips, mouth, nose, eyes and skin. • drying and inflammation of mucous membranes • thirst • flushing • difficulty producing tears • intolerant of contact lenses • itchiness, redness or rashes • thinning or peeling of the skin that was not previously affected • nail fragility or conditions • eye infections • abnormal liver tests • increase in blood cholesterol • muscle, joint or bone pain 	<p>Either a moisturizer or petroleum jelly can be used to soften the lining of the nose, lips and the skin</p> <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • changes in mood including depression or aggression • male breast enlargement • changes in hearing • Skin fissures • Altered mood 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • headache, nausea and vomiting, and visual disturbances can be signs of papilloedema and needs medical investigation • itchy, yellowing skin, lighter coloured stool or darker urine can be signs of jaundice. • Psychotic disorder 	<p>If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.</p> <p>These are very serious side effects, and you may need urgent medical attention or hospitalization</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Allergic reactions

If you think you are having an allergic reaction to ZETIN, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZETIN contains

Active ingredient (main ingredient)	Each ZETIN capsule contains 10 or 25 mg of acitretin as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• maltodextrin• sodium ascorbate• microcrystalline cellulose• gelatin• sodium lauryl sulphate• purified water• black printing ink (shellac glaze, iron oxide black (E172), propylene glycol (E1520))• iron oxide red (E172) (colourant)• iron oxide yellow (E172) (colourant) (25mg only)• titanium dioxide
Potential allergens	May contain trace amounts of phenylalanine and sulfites.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What ZETIN looks like

- **10 mg Capsule*:**

Hard gelatin capsule containing a yellow powder with a white to off-white body and a brown cap printed in black with "A10" on the capsule body.

- **25 mg Capsule*:**

Hard gelatin capsule containing a yellow powder with a yellow to light yellow body and a brown cap printed in black with "A25" on the capsule body.

Available in blister packs of 60 and 100 capsules

* Not all strengths, pack types and/or pack sizes may be available.

- ZETIN 10 mg capsule (blister): AUST R 196005
- ZETIN 25 mg capsule (blister): AUST R 196004

Who distributes ZETIN

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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